

SMG 1121.921

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL AND REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

**OFFICE OF MEDICAL PRODUCTS, TOBACCO AND SPECIALTY
LABORATORY OPERATIONS**

FORENSIC CHEMISTRY LABORATORY

Effective Date: June 6, 2016

1. FORENSIC CHEMISTRY LABORATORY (DLLRKBA).

- A. Serves as FDA's national forensic laboratory resource for method development, analyses and research associated with criminal, regulatory, and counter-terrorism investigations.
- B. Provides rapid response and specialized analytical services in forensic chemistry and molecular/microbiology for activities related to product tampering, counterfeiting, counter terrorism, adulteration/contamination, and product composition. Provides rapid response and analytical problem solving in support of public health emergencies, and Agency forensic investigations.
- C. Works directly with the FDA's Office of Criminal Investigations (OCI) to provide expert technical support and analyses of evidence associated with criminal investigations.
- D. Maintains liaison with national and international scientists and scientific bodies; other Federal, State, and local government officials; and industry personnel having interests pertinent to Center activities regarding forensic investigations.
- E. Develops procedures to establish profiles of adulterants and deleterious substances in foods, feeds, medical products, pharmaceuticals, tobacco and other regulated products.

- F. Advises ORS on new and emerging problems and trends, future program needs and priorities, manpower, equipment, financial needs, and long-range planning.
- G. Conducts collaborative research and develops screening methods to identify unapproved food additives, active pharmaceutical ingredients and chemical analogs.
- H. Designs and conducts experiments to demonstrate the physical and chemical effects of adulterants on food and drug products.
- I. Develops and transfers analytical procedures to other Agency laboratories and develops and transfers tests that can be used by the Agency agents/investigators in the field to counterfeit and potentially adulterated products.
- J. Responds to requests for analytical assistance from other Agency units working on other types of investigations such as counterfeit drugs, illegal steroids, chemical contamination, etc.
- K. Develops joint research projects with universities, industry, and other Federal, State, and international government agencies and provides training in analytical approaches used in forensic problem solving.
- L. Conducts on-site investigations requiring specialized expertise and experience in forensic investigations and maintains state-of-the-art expertise in forensic investigations.
- M. Manages and evaluates program activities, continuously measures achievements, and advises ORS of strategy needed to reach objectives or of the need to adjust objectives.
- N. Manages and implements an accredited quality assurance program.

2. INORGANIC BRANCH (DLLRKBA1).

- A. Works as part of an FCC team to plan, schedule, and manage branch analytical operations and formulate, implement, and coordinate laboratory work with Agency components being supported.
- B. Serves as a resource in scientific knowledge and provides expert advice, testimony, and training regarding forensic techniques and technological developments to scientific bodies and institutions, other Federal, State, and local agencies, foreign counterpart agencies, industries, and courts.

- C. Conducts in-depth method development to identify suspected adulterants and toxic contaminants in foods, pharmaceuticals, animal feeds, medical devices, tobacco and other regulated products.
- D. Operates a quality control program to assure reliability of analytical results.

3. ORGANIC BRANCH (DLLRKBA2).

- A. Works as part of an FCC team to plan, schedule, and manage branch analytical operations and formulate, implement, and coordinate laboratory work with Agency components being supported.
- B. Serves as a resource in scientific knowledge and provides expert advice, testimony, and training regarding forensic techniques and technological developments to scientific bodies and institutions, other Federal, State, and local agencies, foreign counterpart agencies, industries, and courts. Specialized fields of testing include but are not limited to gas and liquid chromatographies with mass spectrometric detection, image analysis, infrared and Raman spectroscopies, capillary electrophoresis, scanning electron microscopy with energy dispersive x-ray analysis, immunoassay based testing, gel electrophoresis and matrix assisted laser desorption ionization mass spectrometry for protein characterization, polymerase chain reactions for detection/speciation of DNA, microbiological and molecular biological practices for use in BSL-2 and BSL-3 laboratories.
- C. Conducts in-depth method development to identify suspected adulterants and toxic contaminants in foods, pharmaceuticals, animal feeds, medical devices, tobacco and other regulated products.
- D. Operates a quality control program to assure reliability of analytical results.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this laboratory were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

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TOBACCO AND SPECIALITY LABORATORY OPERATIONS
FORENSIC CHEMISTRY CENTER**

OFFICE OF THE DIRECTOR

Inorganic Branch	(DLLRKBA)
Organic Branch	(DLLRKBA1)
	(DLLRKBA2)

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Products, Tobacco and Specialty Laboratory Operations, Forensic Chemistry Center organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKBA):

- Inorganic Branch (DLLRKBA1)
- Organic Branch (DLLRKBA2)